TABLE 3—CDRH GUIDANCES AND COLLECTIONS—Continued

COVID–19 guidance title	Citation referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB control No(s).	New collection covered by PHE PRA waiver
		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0595	Updates to FDA every 6 weeks after initial notification on the shortage situation. Voluntary submission of other information.
Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (November 2020).	.....	Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0595	Labeling of the bioburden reduction system.
Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act [MQSA] During the COVID–19 Public Health Emergency (December 2020).	21 CFR Part 900.	.....	0910–0309	Document the time period that the facility was temporarily closed and present information during the facility's MQSA inspection. Document and provide the circumstances re: lack of medical physicist survey within 14 months of the last annual survey. Information on inability to meet the survey timeframes described in the guidance. Provide documentation of the dates and events that led to noncompliance and that facility will ensure compliance as soon as possible after COVID–19 restrictions are lifted.

IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;*
- FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents;* or
- *https://www.regulations.gov.*

Dated: December 29, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–29058 Filed 12–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1414]

Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls Guidance Document: Labeling Natural Rubber Latex Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection for the labeling of natural rubber latex condoms.

DATES: Submit either electronic or written comments on the collection of information by March 5, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 5, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 5, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–N–1414 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls Guidance Document: Labeling Natural Rubber Latex Condoms.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms—21 CFR 884.5300 OMB Control Number 0910–0633—Extension

Under the Medical Device Amendments of 1976 (Pub. L. 94–295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and effectiveness but for which there was sufficient information to establish performance standards to provide such assurance. Accordingly, FDA has established the above captioned Special Controls Guidance Document regarding the labeling of natural rubber latex condoms.

Condoms without spermicidal lubricant containing nonoxynol 9 are classified in class II. They were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101–629), which broadened the definition of class II devices and now permits FDA to establish special controls beyond performance standards, including guidance documents, to help provide reasonable assurance of the safety and effectiveness of such devices.

In December 2000, Congress enacted Public Law 106–554, which directed FDA to ''reexamine existing condom labels'' and ''determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases . . . .'' In response, FDA recommended labeling intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant. FDA expects approximately five new manufacturers or repackagers to enter the market yearly and to collectively have a third-party disclosure burden of 60 hours. The average burden per disclosure was derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

The collection of information under 21 CFR 801.437 does not constitute a ''collection of information'' under the PRA. Rather, it is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300''	5	1	5	12	60

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 29, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–29091 Filed 12–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. Written comments will be accepted and registration is required to present oral comments. Information about the meeting and registration is available at *https://ntp.niehs.nih.gov/go/165.*

DATES:

Meeting: Scheduled for February 2, 2021, 12:30 p.m.–5:00 p.m. Eastern Standard Time (EST). Written Public Comment Submissions: Deadline is January 26, 2021.

Registration for Oral Comments: Deadline is January 26, 2021.

ADDRESSES:

Meeting Web page: The preliminary agenda, registration, and other meeting materials are available at *https://ntp.niehs.nih.gov/go/165.*

Virtual Meeting: The URL for viewing the virtual meeting will be provided on the meeting web page.

FOR FURTHER INFORMATION CONTACT: Dr. Sheena Scruggs, Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 984–287–3355, Fax: 301–451–5759, Email: *sheena.scruggs@nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include presentations from two of the Division of the National Toxicology Program (DNTP)'s research program areas. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (*https://ntp.niehs.nih.gov/go/165*) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting web page.

Meeting Attendance Registration: The meeting is open to the public with time scheduled for oral public comments. Registration is not required to view the virtual meeting; the URL for the virtual meeting is provided on the BSC meeting web page (*https://ntp.niehs.nih.gov/go/165*). TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: NTP invites written public comments. Guidelines for public comments are available at *https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

The deadline for submission of written comments is January 26, 2021. Written public comments should be submitted through the meeting web page. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP web page, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Oral Public Comment Registration: The agenda allows for two formal public comment periods—one comment period for each program area (up to 3 commenters, up to 5 minutes per speaker, per topic). Persons wishing to